RULES
OF
DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-8-32
STANDARDS FOR END STAGE RENAL DIALYSIS CLINICS

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1200-8-32-.01 DEFINITIONS.

(1) Adult. An individual who has capacity and is at least 18 years of age.

(2) Advance Directive. An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.

(3) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

(4) Anticoagulant. A medication or medical technique to prevent or slow down coagulation and clotting.

(5) Anticoagulation. The process of inhibiting the blood clotting mechanism by the administration of certain drugs.

(6) Artificial Kidney. An apparatus which removes metabolic wastes or other poisons from the body when the natural kidneys are not functioning properly. This apparatus may be referred to as a kidney dialyzer.

(7) Board. The Tennessee Board for Licensing Health Care Facilities.

(8) Capacity. An individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health care decision. These regulations do not affect the right of a patient to make health care decisions while having the capacity to do so. A patient shall be presumed to have capacity to make a health care decision, to give or revoke an advance directive, and to designate or disqualify a surrogate. Any person who challenges the capacity of a patient shall have the burden of proving lack of capacity.

(9) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to restore or support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilations or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

(Rule 1200-8-32-.01, continued)

(10) Chronic Hemodialysis. Hemodialysis over a long period of time, usually to the extent of the patient's life or organ transplant.

(11) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

(12) Competent. A patient who has capacity.

(13) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:

(a) the action(s) implemented to prevent the reoccurrence of the unusual event,

(b) the time frames for the action(s) to be implemented,

(c) the person(s) designated to implement and monitor the action(s), and

(d) the strategies for the measurements of effectiveness to be established.

(14) Department. The Tennessee Department of Health.

(15) Designated Physician. A physician designated by an individual or the individual's agent, guardian, or surrogate, to have primary responsibility for the individual's health care or, in the absence of a designation or if the designated physician is not reasonably available, a physician who undertakes such responsibility.

(16) Dialysis. A process by which substances are removed from a patient's body by diffusion and convection from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

(17) Dialysis technician. An individual who is not a registered nurse or physician and who provides dialysis care under the direct supervision of a registered nurse or physician. If unlicensed, this individual may also be known as a patient care technician**,** dialysis assistant or dialysis technician.

(18) Dietitian. A person currently licensed as such by the Tennessee Board of Dietitian/Nutritionist Examiners or exempted from licensure by T.C.A. §63-25-104 and having at least one (1) year of experience in clinical nutrition.

(19) Do Not Resuscitate (DNR) Order. An order entered by the patient's treating physician in the patient's medical record which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.

(20) Emancipated Minor. Any minor who is or has been married or has by court order or otherwise been freed from the care, custody and control of the minor's parents.

(21) Emergency Responder. A paid or volunteer firefighter, law enforcement officer, or other public safety official or volunteer acting within the scope of his or her proper function under law or rendering emergency care at the scene of an emergency.

(22) End-Stage Renal Disease (ESRD). That stage of renal impairment that is or appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

(Rule 1200-8-32-.01, continued)

(23) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(24) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state or federal regulations.

(25) Health Care. Any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. § 32-11-103(5).

(26) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(27) Health Care Decision-maker. In the case of a patient who lacks capacity, the patient's health care decision-maker is one of the following: the patient's health care agent as specified in an advance directive, the patient's court-appointed guardian or conservator with health care decision-making authority, the patient's surrogate as determined pursuant to Rule 1200-8-32-.13 or T.C.A. §33-3-220, the designated physician pursuant to these Rules or in the case of a minor child, the person having custody or legal guardianship.

(28) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(29) Health Care Provider. A person who is licensed, certified or otherwise authorized or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession.

(30) Hospital. Any institution, place, building or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the use, in connection with the services of a physician or dentist, of one (1) or more nonrelated persons who may be suffering from deformity, injury or disease or from any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment.

(31) Hospitalization. The reception and care of any person for a continuous period longer than twenty-four (24) hours, for the purpose of giving advice, diagnosis, nursing service or treatment bearing on the physical health of such person, and maternity care involving labor and delivery for any period of time.

(32) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(33) Individual instruction. An individual's direction concerning a health care decision for the individual.

(44) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(35) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(36) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(37) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(38) Medical Director. A physician who: (1) Is board eligible or board certified in nephrology**,** internal medicine or pediatrics by a professional board, and has at least 12 months of experience or training in the care of patients at ESRD facilities; or (2) During the 5-year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program; and worked within

(Rule 1200-8-32-.01, continued)

the field of kidney dialysis for at least 12 months in the past 5 years. However, in the areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a dialysis facility, another physician may direct the facility, subject to the approval of the Department.

(39) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.

(40) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written, electronic, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients.

(41) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or other medical or surgical treatments to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the patient's representative expresses the goals of the patient.

(42) NFPA. The National Fire Protection Association.

(43) Nurse Manager. A Registered Nurse who is employed full time in a renal dialysis clinic, is currently licensed as such by the Tennessee Board of Nursing, and (1) has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or (2) Has at least 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process. If the Nurse Manager is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience must be in training patients in self-care.

(44) Nurse Practitioner/Clinical Nurse Specialist. A person currently licensed as a registered nurse by the Tennessee Board of Nursing and certified by the American Academy of Nurse Practitioners, the American Nurses Credentialing Center as a nurse practitioner or holds a certification as clinical nurse specialist from the Tennessee Board of Nursing.

(45) Nursing Personnel. Licensed nurses and certified nurse aides**,** who provide nursing care.

(46) On-Duty/On-Site. A staff person who is on the facility's premises and has the obligation to carry out any job responsibilities designated in his/her job description.

(47) On-Site. A staff person who is on the facility's premises but is only required to be on duty during an emergency.

(48) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(49) Patient Care Plan. A written document prepared by the interdisciplinary team for a patient receiving end stage renal disease services.

(Rule 1200-8-32-.01, continued)

(50) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(51) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

(52) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(53) Physician's Assistant. A person who is currently licensed by the Tennessee Board of Medical Examiners and Committee on Physician Assistants and has obtained prescription writing authority pursuant to T.C.A. 63-19-107(2)(A).

(54) Power of Attorney for Health Care. The designation of an agent to make health care decisions for the individual granting the power under T.C.A. Title 34, Chapter 6, Part 2.

(55) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency medical technicians, paramedics, or other emergency services personnel, providers, or entities acting within the usual course of their professions, and other emergency responders.

(56) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the patient's health care needs. Such availability shall include, but not be limited to, availability by telephone.

(57) Referring physician. The physician who refers the patient to the renal dialysis clinic for treatment.

(58) Renal dialysis clinic. Any institution, facility, place or building devoted to the provision of renal dialysis on an outpatient basis to persons diagnosed with end stage renal disease.

(59) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(60) Shall or Must. Compliance is mandatory.

(61) Social Worker. A person who is licensed by the Tennessee Board of Social Worker Certification and Licensure, if applicable, and (1) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school of social work accredited by the Council on Social Work Education; or (2) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program and has established a consultative relationship with a social worker who qualifies in paragraph (1) of this definition.

(62) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(63) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

(64) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(65) Survey. An on-site examination by the Department to determine compliance with state and federal regulations.

(66) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

(Rule 1200-8-32-.01, continued)

(67) Treating Physician. The physician selected by or assigned to the patient and who has the primary responsibility for the treatment and care of the patient. Where more than one physician shares such responsibility, any such physician may be deemed to be the "treating physician."

(68) Universal Do Not Resuscitate Order. A written order that applies regardless of the treatment setting and that is signed by the patient's physician which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The Physician Order for Scope of Treatment (POST) form promulgated by the Board for Licensing Health Care Facilities as a mandatory form shall serve as the Universal DNR according to these rules.

(69) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.

(70) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.

(71) Water Treatment. The process of treating water used for dialysis purposes in order to maintain a continuous water supply that meets AAMI (Association for the Advancement of Medical Instrumentation) standards.

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed December 15, 2005; effective February 28, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-8-32-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or any state, county or local governmental unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any renal dialysis clinic without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Satellite facilities shall be prohibited. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the renal dialysis clinic.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form provided by the department.

(b) Each initial and renewal application for licensure shall be submitted with the fee of one thousand eighty dollars ($1,080.00). All fees submitted are nonrefundable. Any applicant who files an application during the fiscal year must pay the full license fee. A fee must be submitted for each facility at each site for which licensure is being sought.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients shall not be accepted for treatment to the renal dialysis clinic until a license has been issued. Applicants shall not hold themselves out to the public as being a renal dialysis clinic until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules, including submission of all information required by T.C.A. §68-11-206(a)(1) or as later amended, and all information required by the Commissioner.

(Rule 1200-8-32-.02, continued)

(d) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.

(a) For the purpose of licensing, the licensee of a renal dialysis clinic has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the renal dialysis clinic's operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the facility is owned and operated and any ownership interest of the preceding or succeeding entity changes.

(c) Transactions constituting a change of ownership include, but are not limited to, the following:

1. Transfer of the facility's legal title;

2. Lease of the facility's operation;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;

4. One partnership is replaced by another through the removal, addition or substitution of a partner;

5. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

6. The consolidation of a corporate facility owner with one or more corporations; or,

7. Transfers between levels of government.

(d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:

1. Changes in the membership of a corporate board of directors or board of trustees;

2. Two (2) or more corporations merge and the originally-licensed corporation survives;

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or,

5. Corporate stock transfers or sales, even when a controlling interest.

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(Rule 1200-8-32-.02, continued)

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the same legal form as the former owner.

(4) To be eligible for a license or renewal of a license, each renal dialysis clinic shall be periodically inspected for compliance with these rules. If deficiencies are identified, an acceptable plan of correction must be submitted to the department.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-210, and 68-11-216.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Amendment file January 19, 2007; effective April 4, 2007. Amendment filed July 18, 2007; effective October 1, 2007.*

1200-8-32-.03 DISCIPLINARY PROCEDURES.

(1) The board may suspend or revoke a license for:

(a) Violation of federal statutes or rules and regulations;

(b) Violation of state statutes or the rules as set forth in this chapter;

(c) Permitting, aiding or abetting the commission of any illegal act in the renal dialysis clinic;

(d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients of the renal dialysis clinic; and

(e) Failure to renew the license.

(2) The board may consider all factors which it deems relevant, including but not limited to the following, when determining sanctions:

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(b) The character and degree of impact of the violation on the health, safety and welfare of the patients in the facility;

(c) The conduct of the facility in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and

(d) Any prior violations by the facility of statutes, rules or orders of the commissioner or the board.

(3) When a renal dialysis clinic is found by the department to have committed a violation of this chapter, the department will issue to the facility a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies, the facility must return a plan of correction indicating the following:

(a) How the deficiency will be corrected;

(b) The date upon which each deficiency will be corrected;

(c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and

(d) How the corrective action will be monitored to ensure that the deficient practice does not recur.

(Rule 1200-8-32-.03, continued)

(4) Failure to submit a plan of correction in a timely manner, a finding by the department that the plan of correction is unacceptable or failure to comply with the plan of correction, shall subject the renal dialysis clinic's license to possible disciplinary action.

(5) Any licensee or applicant for a license, aggrieved by a decision or action of the department or board, pursuant to this chapter, may request a hearing before the board. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Administrative Procedures Act, T.C.A. §§ 4-5-101, et seq.

(6) Reconsideration and Stays. The Board authorizes the member who chaired the Board for a contested case to be the agency member to make the decisions authorized pursuant to rule 1360-4-1-.18 regarding petitions for reconsiderations and stays in that case.

Authority: *T T.C.A. §§4-5-202, 4-5-204, 4-5-219, 4-5-312, 4-5-316, 4-5-317, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-208, and 68-11-209.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed March 1, 2007; effective May 15, 2007.*

1200-8-32-.04 ADMINISTRATION.

(1) Renal dialysis clinics must have a governing body which is legally responsible for:

(a) The overall operation and maintenance of the facility;

(b) The provision of personnel, facilities, equipment, supplies, and services to patients and families;

(c) Adopting administrative policies regarding patient care;

(d) Appointing an administrator or director responsible for implementing the adopted policies;

(e) Establishing and maintaining a written organizational plan;

(f) Appointing a clinical staff and assuring its competence;

(g) Adopting medical staff bylaws; and

(h) Documenting all of the above.

(2) When licensure is applicable for a particular job, a copy of the current license must be included as a part of the personnel file. Each personnel file shall contain accurate information as to the education, training, experience and personnel background of the employee. Adequate medical screenings to exclude communicable disease shall be required of each employee.

(3) Whenever the rules and regulations of this chapter require that a licensee develop a written policy, plan, procedure, technique, or system concerning a subject, the licensee shall develop the required policy, maintain it and adhere to its provisions. A renal dialysis clinic which violates a required policy also violates the rule and regulation establishing the requirement.

(4) Policies and procedures shall be consistent with professionally recognized standards of practice.

(5) All renal dialysis clinics shall adopt appropriate policies that meet state and federal rules and regulations regarding the testing of patients and staff for human immunodeficiency virus (HIV) and other communicable diseases.

(6) Each renal dialysis clinic utilizing students shall establish policies and procedures for their supervision.

(Rule 1200-8-32-.04, continued)

(7) No renal dialysis clinic shall retaliate against or, in any manner, discriminate against any person because of a complaint made in good faith and without malice to the board, the regional ESRD network, the department, the Adult Protective Services, or the Comptroller of the State Treasury. A renal dialysis clinic shall neither retaliate, nor discriminate, because of information lawfully provided to these authorities, because of a person's cooperation with them, or because a person is subpoenaed to testify at a hearing involving one of these authorities.

(8) Infection Control.

(a) The renal dialysis clinic must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

(b) The renal dialysis clinic must have an infection control program. Members of the medical staff, nursing staff and administrative staff shall develop guidelines and techniques for the prevention, surveillance, control and reporting of facility infections. Duties of the program shall include the establishment of:

1. Written infection control policies;

2. Techniques and systems for identifying, reporting, investigating and controlling infections in the facility;

3. Written procedures governing the use of aseptic techniques and procedures in the facility;

4. Written procedures concerning laundry practices, disposal of environmental and patient wastes, traffic control and visiting rules, sources of air pollution, and routine culturing of autoclaves and sterilizers;

5. A mechanism for tracking incidents related to infectious and communicable diseases;

6. Formal provisions to educate and orient all appropriate personnel in the practice of aseptic techniques such as handwashing, proper grooming, masking, dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies; and

7. Continuing education for all facility personnel on the cause, effect, transmission, prevention, and elimination of infections.

(c) The administrator, the medical staff and Nurse Manager must ensure that the facility-wide performance improvement program and training programs address problems identified by the infection control program and must be responsible for the implementation of successful corrective action plans in affected problem areas.

(d) The facility shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B and C virus and the HIV virus in the event that an employee of the facility, a student studying at the facility, or health care provider rendering services at the facility is exposed to a patient's blood or other body fluid. The testing shall be performed at no charge to the patient, and the test results shall be confidential.

(e) The facility and its employees shall adopt and utilize universal precautions of the Centers for Disease Control and Prevention (CDC) for preventing transmission of infections and communicable diseases.

(Rule 1200-8-32-.04, continued)

(f) Precautions shall be taken to prevent the contamination of sterile supplies by soiled supplies. Sterile supplies shall be packaged and stored in a manner that protects the sterility of the contents. Decontamination and preparation areas shall be separated.

(9) Each renal dialysis clinic shall adopt safety policies for the protection of patients from accident and injury.

(10) Documentation pertaining to the payment agreement between the renal dialysis clinic and the patient shall be completed prior to admission. A copy of the documentation shall be given to the patient and the original shall be maintained in the renal dialysis clinic records.

(11) Dialysis Technicians and Trainees.

(a) An individual may not act as a dialysis technician unless that individual is trained and competent under these rules.

(b) Trainees shall be identified as such during any time spent in the patient treatment areas.

(c) Until the successful completion of the competency evaluation, the trainee may provide patient care only as part of the training program and under the immediate supervision of a registered nurse or an assigned preceptor. A preceptor shall be a licensed nurse**.** If a dialysis technician is deemed competent in one or more of the components outlined in 1200-8-32-.04(12), he/she may perform those duties prior to being deemed competent in all components of the training curriculum. A dialysis technician who has one year of experience in hemodialysis obtained within the last twenty-four (24) months, a recommendation by the supervising nurse to be a preceptor and a current competency skills checklist on file in the facility may be utilized in training as defined in the facility's policies and procedures.

(12) Each training program for dialysis technicians shall develop a written curriculum with objectives and include at a minimum, the following components:

(a) Introduction to dialysis therapies to include history and major issues;

(b) Principles of hemodialysis;

(c) Understanding the individual with kidney failure;

(d) Dialysis procedures;

(e) Hemodialysis devices;

(f) Water treatment following current AAMI guidelines;

(g) Reprocessing, utilizing current AAMI guidelines if the facility practices reuse;

(h) Patient teaching;

(i) Infection Control and safety

1. Universal precautions, aseptic technique, sterile technique, specimen handling;

2. Risks to employees of blood and chemical exposure.

(j) Principles of Quality Improvement and Role of the technician or nurse in QI activities;

(Rule 1200-8-32-.04, continued)

(k) Principles of peritoneal dialysis to include:

1. Periotoneal dialysis delivery systems;

2. Symptoms of peritonitis;

3. Other complications of peritoneal dialysis.

(l) If a dialysis technician is to cannulate access or administer normal saline or lidocaine during initiation or termination of dialysis, the following content must be included:

1. Access to the circulation to include:

(i) fistula creation, development, needle placement, and prevention of complications;

(ii) grafts; materials used, creation, needle placement, and prevention of complications; and

(iii) symptoms to report.

2. Safe administration of medications listed above to include:

(i) identifying the right patient;

(ii) assuring the right medication;

(iii) measuring the right dose;

(iv) ascertaining the right route;

(v) checking the right time for administration;

(vi) reasons for administration;

(vii) potential complications;

(viii) administration limits; and

(ix) information to report and record.

(13) The supervising nurse or registered nurse acting as training instructor shall complete a skills competency checklist to document each dialysis technician trainee's knowledge and skills listed in 1200-8-32-.04(11-12).

(14) Performance Improvement**.**

(a) The renal dialysis clinic must ensure that there is an effective, facility-wide performance improvement program to evaluate patient care and performance of the organization.

(b) The facility must develop and implement plans for improvement to address deficiencies identified by the performance improvement program and must document the outcome of the remedial action.

(Rule 1200-8-32-.04, continued)

(c) The performance improvement program shall be ongoing and have a written plan of implementation which assures that:

1. All organized services related to patient care, including services furnished by a contractor, are evaluated;

2. Nosocomial infections and medication therapy are evaluated; and

3. All services performed in the facility are evaluated as to the appropriateness of diagnosis and treatment.

(d) Performance improvement program records are not disclosable, except when such disclosure is required to demonstrate compliance with this section.

(e) Good faith attempts by the performance improvement program committed to identify and correct deficiencies will not be used as a basis for sanctions.

(f) Written policies, procedures and practice guidelines for management of emergencies and discharge must be developed and implemented.

(15) Personnel records.

(a) A personnel record for each staff member of a facility shall include an application for employment and a record of any disciplinary action taken.

(b) Wage and salary information, time records, an authorization and record of leave shall be maintained but may be kept in a separate location.

(c) A job description shall be maintained which includes the employment requirements and the job responsibilities for each facility staff position.

(d) A personnel record shall be maintained which verifies that each employee meets the respective employment requirements for the staff position held, including annual verification of basic skills and annual evaluation of personnel performance. This evaluation shall be in writing. There shall be documentation to verify that the employee has reviewed the evaluation and has had an opportunity to comment on it.

(e) Training and development activities which are appropriate in assisting the staff in meeting the needs of the patients being served shall be provided for each staff member including HIV and other communicable disease education. The provision of such activities shall be evidenced by documentation in the facility records.

(f) Direct-services staff members shall be competent persons aged eighteen (18) years of age or older.

(g) All new employees, including volunteers, who have routine contact with patients shall have a current tuberculosis test prior to employment or service.

(h) Employees shall have a tuberculin skin test annually and at the time of exposure to active TB and three months after exposure.

(i) Employee records shall include date and type of tuberculin skin test used and date of tuberculin skin test results, date and results of chest x-ray, and any drug treatment for tuberculosis.

(16) Water Treatment and Reuse**.**

(Rule 1200-8-32-.04, continued)

Compliance Required. A facility shall meet the requirements of this section. A facility may follow more stringent requirements for water treatment and reuse of hemodialyzers than the minimum standards required by this section.

(a) The physical space in which water treatment is located must be adequate to allow for maintenance, testing, and repair of equipment. If mixing of dialysate is performed in the same area, the physical space must also be adequate to house and allow for the maintenance, testing and repair of the mixing equipment and for performing the mixing procedures.

(b) The water treatment system components shall be arranged and maintained so that bacterial and chemical contaminant levels in the product water do not exceed the standards for hemodialysis water quality as described in the current Association for the Advancement of Medical Instrumentation (AAMI) standards.

(c) Facility records must include all test results and evidence that the medical director has reviewed the result of water quality testing and directed corrective action when indicated.

(d) Only persons qualified by education or experience may repair or replace components of the water treatment system. Documentation of education or training which qualifies these persons must be maintained on file in the facility.

(e) A facility that reuses hemodialyzers and other dialysis supplies shall meet current AAMI standards.

(17) All health care facilities licensed pursuant to T.C.A. §§ 68-11-201, et seq. shall post the following in the main public entrance:

(a) Contact information including statewide toll-free number of the division of adult protective services, and the number for the local district attorney's office;

(b) A statement that a person of advanced age who may be the victim of abuse, neglect, or exploitation may seek assistance or file a complaint with the division concerning abuse, neglect and exploitation; and

(c) A statement that any person, regardless of age, who may be the victim of domestic violence may call the nationwide domestic violence hotline, with that number printed in boldface type, for immediate assistance and posted on a sign no smaller than eight and one-half inches (8½") in width and eleven inches (11") in height.

Postings of (a) and (b) shall be on a sign no smaller than eleven inches (11") in width and seventeen inches (17") in height.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 71-6-121.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed July 18, 2007; effective October 1, 2007.*

1200-8-32-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

(1) Every person admitted for treatment shall be under the supervision of a physician who holds a license in good standing to practice in Tennessee. The name of the patient's treating physician shall be recorded in the patient's medical record. The renal dialysis clinic shall not admit or continue to treat the following types of patients:

(Rule 1200-8-32-.05, continued)

(a) Persons who pose a clearly documented danger to themselves or to other patients or staff in the renal dialysis clinic;

(b) Persons for whom the renal dialysis clinic is not capable of providing the care ordered by the treating physician. Documentation of the reason(s) for refusal of treatment shall be maintained.

(2) The facility shall ensure that no person on the grounds of race, color, national origin, or handicap, will be excluded from participation in, be denied benefits of, or otherwise subjected to discrimination in the provision of any care or service of the facility. The facility shall protect the civil rights of patients under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

(3) Patients shall be transferred or discharged only for medical reasons, for the welfare of the patient or staff, or for non-payment of fees.

(4) Patients shall be given at least thirty (30) days advance notice of the transfer or discharge unless such delay presents significant risk to the patient or others. When the transfer or discharge is against the patient's wishes, there shall be documentation of efforts to resolve issues leading to the transfer or discharge.

(5) The facility's discharge planning process, including discharge policies and procedures, must be specified in writing and must be developed and/or supervised by a registered nurse, social worker or other appropriately qualified personnel.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-210.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003.*

1200-8-32-.06 BASIC SERVICES.

(1) Medical Staff Services.

(a) Policies and procedures concerning services provided by the renal dialysis clinic shall be available for the treating and/or referring physicians.

(b) Each physician on the medical staff shall have a current license to practice medicine in the State of Tennessee.

(c) The governing body of a facility shall designate a medical director. The Medical Director shall:

1. Delineate the responsibilities of and communicate with treating and /or referring physicians to ensure that each patient receives medical care;

2. Arrange for the delivery of emergency and medical care when the patient's treating and/or referring physician or his/her designated alternate is unavailable;

3. Review reports of all accidents or unusual events occurring on the premises, identifying hazards to health and safety and recommending corrective action to the governing body;

4. Make periodic visits not less than quarterly**,** to the renal dialysis clinic to evaluate the existing conditions and make recommendations for improvements;

5. Review and take appropriate action on reports regarding significant clinical practices, guidelines and outcomes;

6. Oversee so that no infectious health conditions exist which would adversely affect patients;

(Rule 1200-8-32-.06, continued)

7. Advise and provide consultation on matters regarding medical care, standards of care, surveillance and infection control;

8. Develop facility treatment goals which are based on review of aggregate data assessed through quality management activities;

9. Assure adequate training of licensed nurses and dialysis technicians;

10. Assure adequate monitoring of patients and the dialysis process; and

11. Ensure development and implementation of all policies required by this chapter.

(d) The members of the medical staff shall include nephrologists and other physicians with training or demonstrated experience in the care of end stage renal disease patients that consists, at a minimum, of having worked within the field of kidney dialysis for at least 12 months in the past five (5) years.

(e) If a Nurse Practitioner or Physician Assistant is utilized, such individuals shall meet the requirements established by the Board of Nursing (for a Nurse Practitioner) or the Board of Medical Examiners and its Committee on Physician Assistants (for a Physician Assistant).

(f) Medical staff.

1. Each patient shall be under the care of a physician on the medical staff.

2. The care of a pediatric dialysis patient shall be in accordance with this subparagraph. If a pediatric nephrologist is not available as the primary nephrologist, an adult nephrologist may serve as the primary nephrologist with direct patient evaluation by a pediatric nephrologist according to the following schedule:

(i) for patients two years of age or younger – monthly (two of three evaluations may be by phone);

(ii) for patients three to 12 years of age – quarterly; and

(iii) for patients 13 to 18 years of age – as needed or indicated.

3. At a minimum, each patient receiving dialysis in the facility shall be seen by a member of the medical staff monthly**.** Following the initial visit, at the option of the physician, a Nurse Practitioner or Physician Assistant may be utilized on an alternating basis every other month. Home patients shall be seen at least every three months. There shall be evidence of monthly assessment for new and recurrent problems and review of dialysis adequacy.

4. A physician on the medical staff or his/her designee shall be on call and available 24 hours a day to patients and staff.

5. Orders for treatment shall be in writing and signed by the prescribing physician. Routine orders for treatment shall be updated at least annually. Orders for treatment shall include treatment time, dialyzer, blood flow rate, target weight, medications including heparin, and specific infection control measures as needed.

6. If Nurse Practitioners or Physician Assistants are utilized:

(Rule 1200-8-32-.06, continued)

(i) there shall be evidence of communication with the treating physician whenever the Nurse Practitioner or Physician Assistant changes treatment orders;

(ii) the Nurse Practitioner or Physician Assistant may not replace the physician in participating in patient care planning or in quality management activities; and

(iii) the treating physician shall be notified and direct the care of patient medical emergencies.

(g) Patient care plan.

1. A facility shall establish, implement, and enforce a policy whereby patient services are coordinated using an interdisciplinary team approach. The interdisciplinary team shall consist of the patient's primary dialysis physician, registered nurse, social worker, and dietitian.

2. The interdisciplinary team shall develop a written, individualized, comprehensive patient care plan that specifies the services necessary to address the patient's medical, psychological, social, and functional needs, and includes treatment goals.

3. The patient care plan shall include evidence of coordination with other service providers (e.g. hospitals, long term care facilities, home and community support services agencies, or transportation providers) as needed to assure the provision of safe care.

4. The patient care plan shall include evidence of the patient's (or patient's legal representative's) input and participation, unless they refuse to participate. At a minimum, the patient care plan shall demonstrate that the content was shared with the patient or the patient's legal representative.

5. The patient care plan shall be developed within 30 days from the patient's admission to the facility and updated as indicated by any change in the patient's medical, nutritional, or psychosocial condition, or at least every six months. Evidence of the review of the patient care plan with the patient and the interdisciplinary team to evaluate the patient's progress or lack of progress toward the goals of the care plan, and interventions taken when the goals are not achieved, shall be documented and included in the patient's clinical record.

(2) Home Hemo-dialysis services - Reserved.

(3) Nursing Services.

(a) Nursing services to prevent or reduce complications and to maximize the patient's functional status shall be provided to a patient and the patient's family or significant other.

(b) A full-time Nursing Manager shall be employed to manage the provision of patient care.

(c) A registered nurse shall be responsible for:

1. conducting admission nursing assessments;

2. conducting assessments of a patient when indicated by a question relating to a change in the patient's status or at the patient's request;

3. participating in team review of a patient's progress;

(Rule 1200-8-32-.06, continued)

4. recommending changes in treatment based on the patient's current needs;

5. facilitating communication between the patient, patient's family or significant other, and other team members to ensure needed care is delivered;

6. providing oversight and direction to dialysis technicians and licensed practical nurses; and

7. participating in continuous quality improvement activities.

(d) A charge nurse shall be on site and available to the treatment area to provide patient care during all dialysis treatments.

(e) If pediatric dialysis is provided, a registered nurse shall coordinate with a pediatric dialysis center that has a pediatric nephrologist on staff to provide care of pediatric dialysis patients younger than 14 years of age or smaller than 35 kilograms in weight.

(f) Sufficient direct care nursing staff shall be on-site to meet the needs of the patients.

(g) A facility shall provide a nursing station(s) to allow adequate visual monitoring of patients by nursing staff during treatment.

(h) A licensed nurse or dialysis technician shall evaluate each patient before and after treatment according to facility policy and the staff member's level of training. A registered nurse shall conduct a patient assessment when indicated by a question relating to a change in the patient's status or at the patient's request.

(i) The initial nursing assessment shall be initiated by a registered nurse at the time of the first treatment in the facility and completed within the first three treatments.

(j) Each nurse shall have a current Tennessee license to practice nursing in good standing.

(k) Each nurse assigned charge responsibilities shall be a registered nurse and have six months experience in hemodialysis obtained within the last 24 months. A RN who holds a current certification from a nationally recognized board in nephrology nursing or hemodialysis may substitute the certification for the six months experience in dialysis obtained within the last 24 months.

(4) Pharmaceutical Services.

(a) The renal dialysis clinic shall have pharmaceutical services that meet the needs of the patients during dialysis and are in accordance with the Tennessee Board of Pharmacy statutes and rules. The governing body is responsible for implementing policies and procedures that minimize drug errors.

(b) All internal and external medications and preparations intended for human use shall be stored separately. They shall be properly stored in medicine compartments, including cabinets on wheels, or drug rooms. Such compartments, cabinets or drug rooms shall be kept securely locked when not in use, and the key must be in the possession of the supervising nurse or other authorized persons. Poisons or external medications shall not be stored in the same compartment and shall be labeled as such.

(c) Schedule II drugs must be stored behind two (2) separately locked doors at all times and accessible only to persons in charge of administering medication.

(Rule 1200-8-32-.06, continued)

(d) Every renal dialysis clinic shall comply with all state and federal statutes and regulations governing Schedule II drugs.

(e) A notation shall be made in a Schedule II drug book and in the patient's nursing notes each time a Schedule II drug is given. The notation shall include the name of the patient receiving the drug, name of the drug, the dosage given, the method of administration, the date and time given and the name of the practitioner prescribing the drug, and shall be signed or initialed by the prescribing practitioner according to renal dialysis clinic policy.

(f) Medications not specifically limited as to time or number of doses when ordered shall be controlled by automatic stop orders or other methods in accordance with written policies. No Schedule II drug shall be given or continued beyond seventy-two (72) hours without a written order by the physician.

(g) Medication administration records (MAR) shall be checked against the physician's orders. Each dose shall be properly recorded in the clinical record after it has been administered.

(h) Preparation of doses for more than one scheduled administration time shall not be permitted.

(i) Medication shall be administered only by licensed medical or licensed nursing personnel or other licensed health professionals acting within the scope of their licenses, excluding medications as described in 1200-8-32-.04(12)(1).

(j) Unless the unit dose package system is used, individual prescriptions of drugs shall be kept in the original container with the original label intact showing the name of the patient, the drug, the physician, the prescription number and the date dispensed.

(k) Any unused portions of prescriptions shall be turned over to the patient only on a written order by the physician. A notation of drugs released to the patient shall be entered into the medical record. All unused prescriptions left in a renal dialysis clinic must be destroyed on the premises and recorded by a registered nurse. Such record shall be kept in the renal dialysis clinic.

(5) Laboratory Services. The renal dialysis clinic must maintain or have available, either directly or through a contractual agreement, adequate laboratory services to meet the needs of the patients. The renal dialysis clinic must ensure that all laboratory services provided to its patients are performed in a facility licensed in accordance with the Tennessee Medical Laboratory Act (TMLA), if located in Tennessee. All technical laboratory staff shall be licensed in accordance with the TMLA facility and shall be qualified by education, training and experience for the type of services rendered.

(6) Environmental services.

(a) Space and facilities for housekeeping equipment and supply storage shall be provided in each service area. Storage for bulk supplies and equipment shall be located away from patient care areas. The building shall be kept in good repair, clean, sanitary and safe at all times.

(b) The physical environment of the clinic shall be maintained in a safe, clean and sanitary manner. Any condition of the clinic site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances shall not be stored with or near food or medications.

(7) Medical Records.

(a) The renal dialysis clinic shall comply with the Tennessee Medical Records Act, T.C.A. §§ 68-11-301, et seq.

(Rule 1200-8-32-.06, continued)

(b) The renal dialysis clinic must maintain a medical record for each patient. Medical records must be accurate, promptly completed, properly filed and retained, and accessible. The facility must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

(c) All medical records, in either written, electronic, graphic or otherwise acceptable form, must be retained in their original or legally reproduced form for a minimum period of at least ten (10) years after which such records may be destroyed. However, in cases of patients under mental disability or minority, their complete facility records shall be retained for the period of minority or known mental disability, plus one (1) year, or ten (10) years following the discharge of the patient, whichever is longer. Records destruction shall be accomplished by burning, shredding or other effective method in keeping with the confidential nature of the contents. The destruction of records must be made in the ordinary course of business, must be documented and in accordance with the facility's policies and procedures, and no record may be destroyed on an individual basis.

(d) When a renal dialysis clinic closes with no plans of reopening, an authorized representative of the facility shall request final storage or disposition of the facility's medical records by the department. Upon transfer to the department, the facility relinquishes all control over final storage of the records and the files shall become property of the State of Tennessee.

(e) The renal dialysis clinic must have a system of coding and indexing medical records. The system must allow for timely retrieval.

(f) The renal dialysis clinic must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals, and the facility must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the facility only in accordance with federal and state laws, court orders or subpoenas.

(g) The medical record must contain information to justify admission, support the diagnosis, and describe the patient's progress and response to services.

(h) All entries must be legible, complete, dated and authenticated according to facility policy.

(i) All records must document the following:

1. Admitting diagnosis;

2. Documentation of complications;

3. Properly executed informed consent forms for procedures and treatments specified by facility policy, or by federal or state law if applicable, as requiring written patient consent;

4. All practitioners' orders, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

(j) Electronic and computer-generated records and signature entries are acceptable.

(8) Nutrition services.

(a) Nutrition services shall be provided to a patient and the patient's caregiver(s) in order to maximize the patient's nutritional status.

(Rule 1200-8-32-.06, continued)

(b) The dietitian shall be responsible for:

1. conducting a nutrition assessment of a patient;

2. participating in a team review of a patient's progress;

3. recommending therapeutic diets in consideration of cultural or religious preferences and changes in treatment based on the patient's nutritional needs in consultation with the patient's physician;

4. counseling a patient, a patient's family, and a patient's significant other on prescribed diets and monitoring adherence and response to diet therapy. Correctional institutions shall not be required to provide counseling to family members or significant others;

5. referring a patient for assistance with nutrition resources such as financial assistance, community resources or in-home assistance;

6. participating in continuous quality improvement activities; and

7. providing ongoing monitoring of subjective and objective data to determine the need for timely intervention and follow-up. Measurement criteria include but are not limited to weight changes, blood chemistries, adequacy of dialysis, and medication changes which affect nutrition status and potentially cause adverse nutrient interactions.

(c) The collection of objective and subjective data to assess nutrition status shall occur within two weeks or seven treatments from admission to the facility, whichever occurs later. A comprehensive nutrition assessment with an educational component shall be completed within 30 days or 13 treatments from admission to the facility, whichever occurs later.

(d) A nutrition reassessment shall be conducted annually or more often if indicated.

(e) Each facility shall employ or contract with a sufficient number of dietitian(s) to provide clinical nutrition services for each patient.

(f) Nutrition services shall be available at the facility during scheduled treatment times. Access to services may require an appointment.

(9) Social services.

(a) Social services shall be provided to patients and their families and shall be directed at supporting and maximizing the adjustment, social functioning, and rehabilitation of the patient.

(b) The social worker shall be responsible for:

1. conducting psychosocial evaluations;

2. participating in team review of patient progress;

3. recommending changes in services based on the patient's current psychosocial needs;

4. providing case work and group work services to patients and their families in dealing with the special problems associated with end stage renal disease;

(Rule 1200-8-32-.06, continued)

5. except in the case of social workers providing service in correctional institutions, identifying community social agencies and other resources and assisting patients and families in utilizing them; and

6. participating in continuous quality improvement activities.

(c) Initial contact between the social worker and the patient shall occur and be documented within two weeks or seven treatments from the patient's admission, whichever occurs later. A comprehensive psychosocial assessment shall be completed within 30 days or 13 treatments from the patient's admission, whichever occurs later.

(d) A psychosocial reassessment shall be conducted annually or more often if indicated.

(e) Each facility shall employ or contract with a sufficient number of social worker(s) to meet the psychosocial needs of the patients.

(f) Social services shall be available at the facility during the times of patient treatment. Access to social services may require an appointment.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed December 15, 2005; effective February 28, 2006.*

1200-8-32-.07 RESERVED.

1200-8-32-.08 BUILDING STANDARDS.

(1) The renal dialysis clinic must be constructed, arranged, and maintained to ensure the safety of the patient.

(2) The condition of the physical plant and the overall renal dialysis clinic environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

(3) No renal dialysis clinic shall hereafter be constructed, nor shall major alterations be made to existing renal dialysis clinics, or change in a renal dialysis clinic type be made without the prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new renal dialysis clinic is licensed or before any alteration or expansion of a licensed renal dialysis clinic can be approved, the applicant must furnish two (2) complete sets of plans and specifications to the department, together with fees and other information as required. Plans and specifications for new construction and major renovations, other than minor alterations not affecting fire and life safety or functional issues, shall be prepared by or under the direction of a licensed architect and/or a qualified licensed engineer.

(4) After the application and licensure fees have been submitted, the building construction plans must be submitted to the department. All new facilities shall conform to the current addition of the Standard Building Code, the National Fire Protection Code (NFPA), the National Electrical Code, the AIA Guidelines for Design and Construction of Hospital and Health Care Facilities (if applicable), and the U.S Public Health Service Food Code as adopted by the Board for Licensing Health Care Facilities. When referring to height, area or construction type, the Standard Building Code shall prevail. All new and existing facilities are subject to the requirements of the Americans with Disabilities Act (A.D.A.). Where there are conflicts between requirements in the above listed codes and regulations and provisions of this chapter, the most restrictive shall apply.

(5) The codes in effect at the time of submittal of plans and specifications, as defined by these regulations shall be the codes to be used throughout the project.

(Rule 1200-8-32-.08, continued)

(6) Review of plans and specifications shall be acknowledged in writing with copies sent to the architect and the owner, manager or other executive of the institution. The distribution of such review may be modified at the discretion of the department.

(7) All construction shall be executed in accordance with the approved plans and specifications.

(8) All new construction and renovations to renal dialysis clinics, other than minor alterations not affecting fire and life safety or functional issues, shall be performed in accordance with the specific requirements of these regulations governing new construction in renal dialysis clinics, including the submission of phased construction plans and the final drawings and the specifications to each.

(9) In the event submitted materials do not appear to satisfactorily comply with 1200-8-32-.08 (4) the department shall furnish a letter to the party submitting the plans which shall list the particular items in question and request further explanation and/or confirmation of necessary modifications.

(10) Notice of satisfactory review from the department constitutes compliance with this requirement if construction begins within one hundred eighty (180) days of the date of such notice. This approval shall in no way permit and/or authorize any omission or deviation from the requirements of any restrictions, laws, regulations, ordinances, codes or rules of any responsible agency.

(11) Final working drawings and specifications shall be accurately dimensioned and include all necessary explanatory notes, schedules and legends. The working drawings and specifications shall be complete and adequate for contract purposes.

(12) Prior to final inspection, a CD Rom disc, in TIF or DMG format, of the final approved plans including all shop drawings, sprinkler, calculations, hood and duct, addenda, specifications, etc., shall be submitted to the department.

(13) Detailed plans shall be drawn to a scale of at least one-eighth inch equals one foot (1/8" = 1'), and shall show the general arrangement of the building, the intended purpose and the fixed equipment in each room, with such additional information as the department may require. These plans shall be prepared by an architect or engineer licensed to practice in the State of Tennessee. The plans shall contain a certificate signed by the architect or engineer that to the best of his or her knowledge or belief the plans conform to all applicable codes.

(a) Two (2) sets of plans shall be forwarded to the appropriate section of the department for review. After receipt of approval of phased construction plans, the owner may proceed with site grading and foundation work prior to receipt of approval of final plans and specifications with the understanding that such work is at the owner's risk and without assurance that final approval of final plans and specifications shall be granted. Final plans and specifications shall be submitted for review and approval. Final approval must be received before proceeding beyond foundation work.

(b) Review of plans does not eliminate responsibility of owner and/or architect to comply with all rules and regulations.

(14) Specifications shall supplement all drawings. They shall describe the characteristics of all materials, products and devices, unless fully described and indicated on the drawings. Specification copies should be bound in an 8½ x 11 inch folder.

(15) Drawings and specifications shall be prepared for each of the following branches of work: Architectural, Structural, Mechanical, Electrical and Sprinkler.

(16) Architectural drawings shall include:

(Rule 1200-8-32-.08, continued)

(a) Plot plan(s) showing property lines, finish grade, location of existing and proposed structures, roadways, walks, utilities and parking areas;

(b) Floor plan(s) showing scale drawings of typical and special rooms, indicating all fixed and movable equipment and major items of furniture;

(c) Separate life safety plans showing the compartment(s), all means of egress and exit markings, exits and travel distances, dimensions of compartments and calculation and tabulation of exit units. All fire and smoke walls must be identified;

(d) The elevation of each facade;

(e) The typical sections throughout the building;

(f) The schedule of finishes;

(g) The schedule of doors and windows;

(h) Roof plans;

(i) Details and dimensions of elevator shaft(s), car platform(s), doors, pit(s), equipment in the machine room, and the rates of car travel must be indicated for elevators; and

(j) Code analysis.

(17) Structural drawings shall include:

(a) Plans of foundations, floors, roofs and intermediate levels which show a complete design with sizes, sections and the relative location of the various members;

(b) Schedules of beams, girders and columns; and

(c) Design live load values for wind, roof, floor, stairs, guard, handrails, and seismic.

(18) Mechanical drawings shall include:

(a) Specifications which show the complete heating, ventilating, fire protection, medical gas systems and air conditioning systems;

(b) Water supply, sewerage and HVAC piping systems;

(c) Pressure relationships shall be shown on all floor plans;

(d) Heating, ventilating, HVAC piping, medical gas systems and air conditioning systems with all related piping and auxiliaries to provide a satisfactory installation;

(e) Water supply, sewage and drainage with all lines, risers, catch basins, manholes and cleanouts clearly indicated as to location, size, capacities, etc., and location and dimensions of septic tank and disposal field; and,

(f) Color coding to show clearly supply, return and exhaust systems.

(19) Electrical drawings shall include:

(Rule 1200-8-32-.08, continued)

(a) A certification that all electrical work and equipment is in compliance with all applicable local codes and laws, and that all materials are currently listed by recognized testing laboratories;

(b) All electrical wiring, outlets, riser diagrams, switches, special electrical connections, electrical service entrance with service switches, service feeders and characteristics of the light and power current, and transformers when located within the building;

(c) The electrical system shall comply with applicable codes, and shall include:

1. The fire alarm system; and

2. The emergency power system including automatic services as defined by the codes.

(d) Color coding to show all items on emergency power.

(20) Sprinkler drawings shall include:

(a) Shop drawings, hydraulic calculations, and manufacturer cut sheets;

(b) Site plan showing elevation of fire hydrant to building, test hydrant, and flow data (Data from within a 12 month period); and

(c) Show “Point of Service’ where water is used exclusively for fire protection purposes.

(21) No system of water supply, plumbing, sewage, garbage or refuse disposal shall be installed nor shall any existing system be materially altered or extended until complete plans and specifications for the installation, alteration or extension have been submitted to the department and show that all applicable codes have been met and necessary approval has been obtained.

(a) Before the facility is used, the water supply system shall be approved by the Tennessee Department of Environment and Conservation.

(b) Sewage shall be discharged into a municipal system or approved package system where available; otherwise, the sewage shall be treated and disposed of in a manner of operation approved by the Department of Environment and Conservation and shall comply with existing codes, ordinances and regulations which are enforced by cities, counties or other areas of local political jurisdiction.

(c) Water distribution systems shall be arranged to provide hot water at each hot water outlet at all times. Hot water at shower, bathing and hand washing facilities shall be between 105°F.and 115°F.

(22) The following alarms are required and shall be monitored twenty-four (24) hours per day:

(a) Fire alarms; and

(b) Generators (if applicable)

(23) A negative air pressure shall be maintained in the soiled utility area, toilet room, janitor’s closet, dishwashing and other such soiled spaces, and a positive air pressure shall be maintained in all clean areas including, but not limited to, clean linen rooms and clean utility rooms.

(24) With the submission of plans the facility shall specify the evacuation capabilities of the patients as defined in the National Fire Protection Code (NFPA). This declaration will determine the design and construction requirements of the facility.

(Rule 1200-8-32-.08, continued)

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Repeal and new rule filed December 15, 2005; effective February 28, 2006.*

1200-8-32-.09 LIFE SAFETY.

(1) Any renal dialysis clinic which complies with the required applicable building and fire safety regulations at the time the board adopts new codes or regulations will, so long as such compliance is maintained (either with or without waivers of specific provisions), be considered to be in compliance with the requirements of the new codes or regulations.

(2) The renal dialysis clinic shall provide fire protection by the elimination of fire hazards, by the installation of necessary fire fighting equipment and by the adoption of a written fire control plan. All fires which result in a response by the local fire department shall be reported to the department within seven (7) days. The report shall contain sufficient information to ascertain the nature and location of the fire, its probable cause and any injuries incurred by any person or persons as a result of the fire. Initial reports by the facility may omit the name(s) of patient(s) and parties involved, however, should the department find the identities of such persons to be necessary to an investigation, the facility shall provide such information.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Repeal and new rule filed December 15, 2005; effective February 28, 2006.*

1200-8-32-.10 INFECTIOUS AND HAZARDOUS WASTE.

(1) Each renal dialysis clinic must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous wastes. These policies and procedures must comply with the standards of this section and all other applicable state and federal regulations.

(2) The following waste shall be considered to be infectious waste:

(a) Waste contaminated by patients who are isolated due to communicable disease, as provided in the U.S. Centers for Disease Control “Guidelines for Isolation Precautions in Hospitals”;

(b) Cultures and stocks of infectious agents including specimen cultures collected from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, waste from the production of biologicals, discarded live and attenuated vaccines, culture dishes and devices used to transfer, inoculate, and mix cultures;

(c) Waste human blood and blood products such as serum, plasma, and other blood components;

(d) All discarded sharps (e.g., hypodermic needles, syringes, pasteur pipettes, broken glass, scalpel blades) used in patient care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories; or,

(e) Other waste determined to be infectious by the facility in its written policy.

(3) Infectious and hazardous waste must be segregated from other waste at the point of generation, i.e., the point at which the material becomes a waste within the facility.

(4) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal.

(Rule 1200-8-32-.10, continued)

Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported prior to treatment and disposal.

(a) Contaminated sharps must be directly placed in leakproof, rigid, and puncture-resistant containers which must then be tightly sealed.

(b) Whether disposable or reusable, all containers, bags, and boxes used for containment and disposal of infectious waste must be conspicuously identified. Packages containing infectious waste which pose additional hazards (e.g., chemical, radiological) must also be conspicuously identified to clearly indicate those additional hazards.

(c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste.

(d) Opaque packaging must be used for pathological waste.

(5) After packaging, waste must be handled and transported by methods ensuring containment and preserving the integrity of the packaging, including the use of secondary containment where necessary.

(a) Infectious waste must not be compacted or ground (i.e., in a mechanical grinder) prior to treatment, except that pathological waste may be ground prior to disposal.

(b) Plastic bags of infectious waste must be transported by hand.

(6) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons Waste must be stored in a manner and location which affords protection from animals, precipitation, wind, and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.

(7) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the facility must ensure that proper actions are immediately taken to:

(a) Isolate the area from the public and all except essential personnel;

(b) To the extent practicable, repackage all spilled waste and contaminated debris in accordance with the requirements of this rule;

(c) Sanitize all contaminated equipment and surfaces appropriately. Written policies and procedures must specify how this will be done; and

(d) Complete an incident report and maintain a copy on file.

(8) Except as provided otherwise in this rule, a facility must treat or dispose of infectious waste by one or more of the methods specified in this paragraph.

(a) A facility may treat infectious waste in an on-site sterilization or disinfection device, or in an incinerator or a steam sterilizer, which has been designed, constructed, operated and maintained so that infectious waste treated in such a device is rendered non-infectious and is, if applicable, authorized for that purpose pursuant to current rules of the Department of Environment and Conservation. A valid permit or other written evidence of having complied with the Tennessee Air Pollution Control Regulations shall be available for review, if required. Each

(Rule 1200-8-32-.10, continued)

sterilizing or disinfection cycle must contain appropriate indicators to assure conditions were met for proper sterilization or disinfection of materials included in the cycle, and records kept. Proper operation of such devices must be verified at least monthly, and records of these monthly checks shall be available for review. Waste that contains toxic chemicals that would be volatilized by steam must not be treated in steam sterilizers. Infectious waste that has been rendered to carbonized or mineralized ash shall be deemed non-infectious. Unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation, such ash shall be disposable as a non-hazardous solid waste under current rules of the Department of Environment and Conservation.

(b) The facility may discharge liquid or semi-liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. § 69-3-101, et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.

(c) Any health care facility accepting waste from another state must promptly notify the Department of Environment and Conservation, county, and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.

(9) The facility may have waste transported off-site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off-site location is in Tennessee, the facility must ensure that it has all necessary state and local approvals, and such approvals shall be available for review. If the off-site location is in another state, the facility must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable federal and state requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.

(10) All garbage, trash and other non-infectious waste shall be stored and disposed of in a manner that shall not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, constructed of easily cleanable material and shall be kept on elevated platforms.

Authority: *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003.*

1200-8-32-.11 RECORDS AND REPORTS.

(1) The renal dialysis clinic shall report each case of communicable disease to the local county health officer in the manner provided by existing regulations. Failure to report a communicable disease may result in disciplinary action, including revocation of the facility's license.

(2) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.

(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:

1. medication errors;

2. aspiration in a non-intubated patient related to conscious/moderate sedation;

(Rule 1200-8-32-.11, continued)

3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;

4. volume overload leading to pulmonary edema;

5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;

6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;

7. burns of a second or third degree;

8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;

9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:

   (i) procedure related injury requiring repair or removal of an organ;

   (ii) hemorrhage;

   (iii) displacement, migration or breakage of an implant, device, graft or drain;

   (iv) post operative wound infection following clean or clean/contaminated case;

   (v) any unexpected operation or reoperation related to the primary procedure;

   (vi) hysterectomy in a pregnant woman;

   (vii) ruptured uterus;

   (viii) circumcision;

   (ix) incorrect procedure or incorrect treatment that is invasive;

   (x) wrong patient/wrong site surgical procedure;

   (xi) unintentionally retained foreign body;

   (xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;

   (xiii) criminal acts;

   (xiv) suicide or attempted suicide;

   (xv) elopement from the facility;

   (xvi) infant abduction, or infant discharged to the wrong family;

(Rule 1200-8-32-.11, continued)

(xvii) adult abduction;

(xviii) rape;

(xix) patient altercation;

(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;

(xxi) restraint related incidents; or

(xxii) poisoning occurring within the facility.

(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:

1. strike by the staff at the facility;

2. external disaster impacting the facility;

3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and

4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.

(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.

(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.

(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.

(Rule 1200-8-32-.11, continued)

(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.

(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.

(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.

(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.

(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.

(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.

(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.

(3) The renal dialysis clinic shall retain legible copies of the following records and reports for thirty-six months following their issuance. They shall be maintained in a single file and shall be made available for inspection during normal business hours to any person who requests to view them:

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(d) Department licensure and fire safety inspections and surveys;

(Rule 1200-8-32-.11, continued)

(e) Federal Health Care Financing Administration surveys and inspections, if any;

(f) Orders of the Commissioner or Board, if any;

(g) Comptroller of the Treasury's audit reports and findings, if any; and,

(h) Maintenance records of all safety equipment.

(4) Copies of the records and reports listed above, with the exception of patient records, shall be maintained in a location convenient to the public and, during normal business hours. They shall be made available for inspection by any person who requests to view them. Each patient and/or person assuming any financial responsibility for a patient shall be fully informed, before or at the time of admission, of the availability of these reports.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-210, and 68-11-211.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003.*

1200-8-32-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the facility must notify the department within seven (7) business days and the Tennessee Department of Human Services, Adult Protective Services immediately as required by T.C.A. §71-6-101 et seq;

(c) To refuse treatment. The patient must be informed of the consequences of that decision. The refusal and its reason must be reported to the physician and documented in the medical record;

(d) To refuse experimental treatment and drugs. The patient's or health care decision maker's written consent for participation in research must be obtained and retained in his or her medical record;

(e) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The renal dialysis clinic must have policies to govern access and duplication of the patient's record;

(f) To have appropriate assessment and management of pain; and

(g) To be involved in all aspects of their care.

(2) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment (including resuscitative services). This right of self-determination may be effectuated by an advance directive.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed December 15, 2005; effective February 28, 2006.*

1200-8-32-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(Rule 1200-8-32-.13, continued)

(1) Pursuant to this Rule, each end stage renal dialysis clinic shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient upon the death of the patient. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient lacks capacity, and ceases to be effective upon a determination that the patient has recovered capacity.

(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the patient's best interest. In determining the patient's best interest, the agent shall consider the patient's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A patient having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(Rule 1200-8-32-.13, continued)

(13) A patient having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient who is an adult or emancipated minor if and only if:

1. the patient has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient who lacks capacity, the patient's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient is receiving health care.

(d) The patient's surrogate shall be an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the patient's spouse, unless legally separated;

2. the patient's adult child;

3. the patient's parent;

4. the patient's adult sibling;

5. any other adult relative of the patient; or

6. any other adult who satisfies the requirements of 1200-8-32-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient shall be eligible to serve as the patient's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

(Rule 1200-8-32-.13, continued)

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests;

2. The proposed surrogate's regular contact with the patient prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the patient lacks capacity and none of the individuals eligible to act as a surrogate under 1200-8-32-.13(16)(c) thru 1200-8-32-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the patient after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the patient's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient may make all health care decisions for the patient that the patient could make on the patient's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-8-32-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

(Rule 1200-8-32-.13, continued)

1. the employee so designated is a relative of the patient by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the patient's individual instructions and may not revoke the patient's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the patient's current clinical record and communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.

(19) Except as provided in 1200-8-32-.13(20) thru 1200-8-32-.13(22), a health care provider or institution providing care to a patient shall:

(a) comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient; and

(b) comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or to a person then authorized to make health care decisions for the patient.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-8-32-.13(20) thru 1200-8-32-.13(22) shall:

(Rule 1200-8-32-.13, continued)

(a) promptly so inform the patient, if possible, and any person then authorized to make health care decisions for the patient;

(b) provide continuing care to the patient until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or person then authorized to make health care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient has the same rights as the patient to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:

1. with the consent of the patient; or

(Rule 1200-8-32-.13, continued)

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the patient is an adult who is capable of making an informed decision, the patient's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient be resuscitated by the person authorized to consent on the patient's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's record.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed December 15, 2005; effective February 28, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-8-32-.14 DISASTER PREPAREDNESS.

(1) The administration of every facility shall have in effect and available for all supervisory personnel and staff, written copies of the following required disaster plans, for the protection of all persons in the event of fire and other emergencies, for evacuation to areas of refuge and /or evacuation from the building. A detailed log with staff signatures of training received shall be maintained. All employees

(Rule 1200-8-32-.14, continued)

shall be trained annually as required in the following plans and shall be kept informed with respect to their duties under the plans. A copy of the plans shall be readily available at all times in the telephone operator's position or at the security center. Each of the following plans shall be exercised annually prior to the month listed in each plan:

(a) Fire Safety Procedures Plan (to be exercised at any time during the year) shall include:

1. Minor fires;

2. Major fires;

3. Fighting the fire;

4. Evacuation procedures; and

5. Staff functions by department and job assignment.

(b) Tornado/Severe Weather Procedures Plan shall include:

1. Staff duties by department and job assignment; and

2. Evacuation procedures.

(c) Bomb Threat Procedures Plan (to be exercised at any time during the year) shall include:

1. Staff duties;

2. Search team, searching the premises;

3. Notification of authorities;

4. Location of suspicious objects; and

5. Evacuation procedures.

(d) Floods Procedures Plan, if applicable, shall include:

1. Staff duties;

2. Evacuation procedures; and

3. Safety procedures following the flood.

(e) Severe Cold Weather and Severe Hot Weather Procedures Plans shall include:

1. Staff duties;

2. Equipment failures;

3. Insufficient HVAC on emergency power; and

4. Evacuation procedures.

(f) Earthquake Disaster Procedures Plan shall include:

(Rule 1200-8-32-.14, continued)

1. Staff duties;

2. Evacuation procedures;

3. Safety procedures; and

4. Emergency services.

All facilities shall participate in the Tennessee Emergency Management local/county emergency plan on an annual basis. Participation includes but is not limited to filling out and submitting a questionnaire on a form to be provided by the Tennessee Emergency Management Agency. Documentation of participation shall be maintained and shall be made available to survey staff as proof of participation.

(2) In the event of natural disaster or electrical power failure, no new dialysis procedures shall be begun, and dialysis procedures in progress shall be brought to conclusion as soon as possible.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003.*

1200-8-32-.15 APPENDIX I

(1) Physician Orders for Scope of Treatment (POST) Form

COPY OF FORM SHALL ACCOMPANY PATIENT WHEN TRANSFERRED OR DISCHARGED	
Physician Orders for Scope of Treatment (POST) This is a Physician Order Sheet based on the medical conditions and wishes of the person identified at right ("patient"). Any section not completed indicates full treatment for that section. When need occurs, first follow these orders, then contact physician.	Patient's Last Name First Name/Middle Initial Date of Birth
Section A Check One Box Only	CARDIOPULMONARY RESUSCITATION (CPR): Patient has no pulse and/or is not breathing. ☐ Resuscitate (CPR) ☐ Do Not Attempt Resuscitate (DNR/no CPR) When not in cardiopulmonary arrest, follow orders in B, C, and D.
Section B Check One Box Only	MEDICAL INTERVENTIONS. Patient has pulse and/or is breathing. ☐ Comfort Measures Treat with dignity and respect. Keep clean, warm, and dry. Use medication by any route, positioning, wound care and other measures to relieve pain and suffering. Use oxygen, suction and manual treatment of airway obstruction as needed for comfort. Do not transfer to hospital for life-sustaining treatment. Transfer only if comfort needs cannot be met in current location. ☐ Limited Additional Interventions Includes care described above. Use medical treatment, IV fluids and cardiac monitoring as indicated. Do not use intubation, advanced airway interventions, or mechanical ventilation. Transfer to hospital if indicated. Avoid intensive care. ☐ Full Treatment. Includes care above. Use intubation, advanced airway interventions mechanical ventilation, and cardioversion as indicated. Transfer to hospital if indicated. Include intensive care. Other Instructions:_____
Section C	ANTIBIOTICS – Treatment for new medical conditions: ☐ No Antibiotics

(Rule 1200-8-32-.15, continued)

Check One Box Only	☐ Antibiotics Other Instructions:_____
Section D Check One Box Only in Each Column	MEDICALLY ADMINISTERED FLUIDS AND NUTRITION. Oral fluids and nutrition must be offered if medically feasible. ☐ No IV fluids (provide other measures to assure comfort) ☐ No feeding tube ☐ IV fluids for a defined trial period ☐ Feeding tube for a defined trial period ☐ IV fluids long-term if indicated ☐ Feeding tube long-term Other Instructions:_____

Section E Must be Completed	Discussed with: ☐ Patient/Resident ☐ Health care agent ☐ Court-appointed guardian ☐ Health care surrogate ☐ Parent of minor ☐ Other:_____(Specify)	The Basis for These Orders Is: (Must be completed) ☐ Patient's preferences ☐ Patient's best interest (patient lacks capacity or preferences unknown) ☐ Medical indications ☐ (Other)_____	
	Physician Name (Print)	Physician Phone Number	Office Use Only
	Physician Signature (Mandatory)	Date	

COPY OF FORM SHALL ACCOMPANY PATIENT WHEN TRANSFERRED OR DISCHARGED

HIPAA PERMITS DISCLOSURE OF POST TO OTHER HEALTH CARE PROFESSIONALS AS NECESSARY

Signature of Patient, Parent of Minor, or Guardian/Health Care Representative

Significant thought has been given to life-sustaining treatment. Preferences have been expressed to a physician and/or health care professional(s). This document reflects those treatment preferences.

(If signed by surrogate, preferences expressed must reflect patient's wishes as best understood by surrogate.)

Signature	Name (print)	Relationship (write "self" if patient)

Contact Information

Surrogate	Relationship	Phone Number	
Health Care Professional Preparing Form	Preparer Title	Phone Number	Date Prepared

Directions for Health Care Professionals

Completing POST

Must be completed by a health care professional based on patient preferences, patient best interest, and medical indications.

POST must be signed by a physician to be valid. Verbal orders are acceptable with follow-up signature by physician in accordance with facility/community policy.

Photocopies/faxes of signed POST forms are legal and valid.

Using POST

Any incomplete section of POST implies full treatment for that section.

No defibrillator (including AEDs) should be used on a person who has chosen "Do Not Attempt Resuscitation".

Oral fluids and nutrition must always be offered if medically feasible.

When comfort cannot be achieved in the current setting, the person, including someone

(Rule 1200-8-32-.15, continued)

with "Comfort Measures Only", should be transferred to a setting able to provide comfort (e.g., treatment of a hip fracture).

IV medication to enhance comfort may be appropriate for a person who has chosen "Comfort Measures Only".

Treatment of dehydration is a measure which prolongs life. A person who desires IV fluids should indicate "Limited Interventions" or "Full Treatment".

A person with capacity, or the surrogate of a person without capacity, can request alternative treatment.

Reviewing POST

This POST should be reviewed if:

(1) The patient is transferred from one care setting or care level to another, or
(2) There is a substantial change in the patient's health status, or
(3) The patient's treatment preferences change.

Draw line through sections A through E and write "VOID" in large letters if POST is replaced or becomes invalid.

Approved by Tennessee Department of Health, Board for Licensing Health Care Facilities, February 2, 2005

COPY OF FORM SHALL ACCOMPANY PATIENT WHEN TRANSFERRED OR DISCHARGED

DO NOT ALTER THIS FORM!

(2) Advance Care Plan Form

ADVANCE CARE PLAN

Instructions: Competent adults and emancipated minors may give advance instructions using this form or any form of their own choosing. To be legally binding, the Advance Care Plan must be signed and either witnessed or notarized.

I, _____, hereby give these advance instructions on how I want to be treated by my doctors and other health care providers when I can no longer make those treatment decisions myself.

Agent: I want the following person to make health care decisions for me:

Name:_____ Phone #: _____ Relation: _____

Address: _____

Alternate Agent: If the person named above is unable or unwilling to make health care decisions for me, I appoint as alternate:

Name:_____ Phone #: _____ Relation: _____

Address: _____

Quality of Life:

I want my doctors to help me maintain an acceptable quality of life including adequate pain management. A quality of life that is unacceptable to me means when I have any of the following conditions (you can check as many of these items as you want):

☐ Permanent Unconscious Condition: I become totally unaware of people or surroundings with little chance of ever waking up from the coma.

☐ Permanent Confusion: I become unable to remember, understand or make decisions. I do not recognize loved ones or cannot have a clear conversation with them.

☐ Dependent in all Activities of Daily Living: I am no longer able to talk clearly

(Rule 1200-8-32-.15, continued)

or move by myself. I depend on others for feeding, bathing, dressing and walking. Rehabilitation or any other restorative treatment will not help.

☐ End-Stage Illnesses: I have an illness that has reached its final stages in spite of full treatment. Examples: Widespread cancer that does not respond anymore to treatment; chronic and/or damaged heart and lungs, where oxygen needed most of the time and activities are limited due to the feeling of suffocation.

Treatment:

If my quality of life becomes unacceptable to me and my condition is irreversible (that is, it will not improve), I direct that medically appropriate treatment be provided as follows. Checking "yes" means I WANT the treatment. Checking "no" means I DO NOT want the treatment.

☐ Yes ☐ No	CPR (Cardiopulmonary Resuscitation): To make the heart beat again and restore breathing after it has stopped. Usually this involves electric shock, chest compressions, and breathing assistance.
☐ Yes ☐ No	Life Support/Other Artificial Support: Continuous use of breathing machine, IV fluids, medications, and other equipment that helps the lungs, heart, kidneys and other organs to continue to work.
☐ Yes ☐ No	Treatment of New Conditions: Use of surgery, blood transfusions, or antibiotics that will deal with a new condition but will not help the main illness.
☐ Yes ☐ No	Tube feeding/IV fluids: Use of tubes to deliver food and water to patient's stomach or use of IV fluids into a vein which would include artificially delivered nutrition and hydration.

Other instructions, such as burial arrangements, hospice care, etc.:_____

(Attach additional pages if necessary)

Organ donation (optional): Upon my death, I wish to make the following anatomical gift (please mark one):

☐ Any organ/tissue ☐ My entire body ☐ Only the following organs/tissues: _____

SIGNATURE

Your signature should either be witnessed by two competent adults or notarized. If witnessed, neither witness should be the person you appointed as your agent, and at least one of the witnesses should be someone who is not related to you or entitled to any part of your estate.

Signature: _____ DATE:_____
(Patient)

Witnesses:

1, I am a competent adult who is not named as the agent. I witnessed the patient's signature on this form. _____
Signature of witness number 1

2. I am a competent adult who is not named as the agent. I am not related to the patient by blood, marriage, or adoption and I would not be entitled to any portion of the patient's estate upon his or her death under any existing will or codicil or by operation of law. I witnessed the patient's signature on this form. _____
Signature of witness number 2

(Rule 1200-8-32-.15, continued)
This document may be notarized instead of witnessed:

STATE OF TENNESSEE
COUNTY OF_____

I am a Notary Public in and for the State and County named above. The person who signed this instrument is personally known to me (or proved to me on the basis of satisfactory evidence) to be the person who signed as the "patient". The patient personally appeared before me and signed above or acknowledged the signature above as his or her own. I declare under penalty of perjury that the patient appears to be of sound mind and under no duress, fraud, or undue influence.

My commission expires: _____ _____
Signature of Notary Public

WHAT TO DO WITH THIS ADVANCE DIRECTIVE

- Provide a copy to your physician(s)
- Keep a copy in your personal files where it is accessible to others
- Tell your closest relatives and friends what is in the document
- Provide a copy to the person(s) you named as your health care agent

Approved by Tennessee Department of Health, Board for Licensing Health Care Facilities, February 2, 2005
Acknowledgement to Project GRACE for inspiring the development of this form.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-209, 68-11-224, and 68-11-1805.* ***Administrative History:*** *Original rule filed February 16, 2007; effective May 2, 2007.*